

Appl. No. 09/655,232  
Amdt. AF dated May 27, 2004  
Reply to Final Office Action of January 30, 2004

### REMARKS

Applicant has received and carefully reviewed the Final Office Action mailed on January 30, 2004. Claims 6-9, 13-21 and 24-26 are under consideration, with claims 27-42 withdrawn from consideration. Reconsideration and reexamination are respectfully requested.

As illustrated above, Applicant has made several technical amendments to the preambles of claims 19-21 and 24-26. The claim preambles now recite "The balloon catheter" instead of "The means for measuring". By this amendment, dependent claims 19-21 and 24-26 are placed in agreement with their base claim, making the claims more amenable to analysis on appeal. As the amendment does not create any substantial new issues or require a search, it is requested that the amendments to these claims be entered.

On page 2 of the Office Action, claims 6-9, 13-21 and 24-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ishida, et al. (U.S. Patent No. 5,002,556), in view of Becker et al. (U.S. Patent No. 5,021,043), and Rowland et al. (U.S. Patent No. 5,427,115). After reviewing the rejection and the cited references, Applicant respectfully traverses the rejections based both on technical and substantive grounds.

Before addressing the substantive rejections, Applicant disagrees with the propriety of the stated rejections in a Final Office Action. Applicant notes that the Final Rejection contains a new rejection, based on newly cited references, of claimed subject matter that was previously pending in the case. In particular, in the previous amendment, previously pending claim 12 was cancelled and incorporated into independent claim 6. Therefore the subject matter now contained in claim 6 was already claimed before the Amendment. However, in the previous Office Action, then pending claim 12 was rejected only on the basis of 35 U.S.C. §103(a) using Ishida et al. in view of Becker et al. The Final Office Action includes only a rejection of claim 6 (corresponding to the same subject matter as previous claim 12) using Ishida et al. in view of Becker et al. and Rowland et al. The rejection that the Examiner has stated for claim 6 is, therefore, a new rejection of claimed subject matter that was previously claimed. The rejection is based on a newly cited combination of references and was not necessitated by the amendment, and is not properly part of a Final Office Action. More specifically, because then pending claim 12 was not rejected by the same combination as is relied upon for now pending claim 6, the Office Action should not be final under MPEP 706.07(a):

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Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

In light of the above, Applicant requests withdrawal of the finality of the Office Action. Absent such withdrawal by the Examiner, Applicants will file a petition formally requesting a decision of the propriety of the final action.

Also, Applicant notes that the Examiner did not provide any response to the arguments made by Applicant in favor of the patentability of previously pending claim 12. Because now pending claim 6 corresponds to previous claim 12, the Examiner should have considered and responded to the traversal of that rejection, as called for by MPEP 707.07(f). However, where a new rejection is stated, there would be less for the Examiner to say in response to Applicant's arguments, as the new rejection would itself be a response to arguments. Since the Examiner did not respond to the arguments presented, it is again believed that the present rejection of claim 6 is improper, as it is a new rejection of previously claimed subject matter.

Turning to substantive matters, claim 6, as previously presented, recites:

6. A marker system comprising:  
an elongate catheter body;  
an expandable member attached to a distal end of the catheter body; and  
opaque markers positioned on the expandable member, wherein the  
opaque markers are arranged in a pattern.

The Examiner cites Ishida et al. to illustrate the general concept of having opaque markers on an expandable member, while citing secondary references to illustrate in addition the use of certain materials and marker types. Applicant respectfully traverses the characterization of the primary reference.

Ishida et al. note "The material of the balloon 5 may be mixed with X-ray opaque substances such as platinum, gold or the like which constitutes a marker." Ishida et al. at column 4, lines 19-21. However, the fact that the balloon is described as a marker is not disclosure of placement of an opaque marker on an expandable member, as recited. The Examiner cites Figure 11 of Ishida et al. As the Examiner notes, Ishida et al. state "the distal portion 24c of the balloon 24 may be made solid, and a belt-type marker 24d made of X-ray opaque substance as

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described above may be fixed to or embedded in the outer peripheral surface of the portion 24c." Ishida et al. at column 6, lines 54-58. However, claim 6 recites "opaque markers positioned on the expandable member." Ishida et al. disclose a marker placed on a solid portion 24c formed of balloon material. Because element 24c is a solid portion, it would clearly be inexpandable. Placement of a marker 24d on an inexpandable, solid element 24c is quite different from placing the marker on an expandable member, as recited. Indeed, given Ishida et al.'s teachings of using the balloon material as a whole as a marker, there would be no motivation to add another marker on top of the expandable balloon. Therefore, regardless of what is taught by the other cited references, the modification of Ishida et al. to include a marker placed on an expandable member is believed improper under MPEP 2143.01.

In light of the above, Ishida et al. do not disclose or fairly suggest opaque markings of any sort on a balloon, instead suggesting that the balloon be formed of a material that is radiopaque. It is not fairly disclosed why or how one would form the balloon of Ishida et al. with a pattern of radiopaque markings. In summary, Ishida et al. by itself renders the addition of markings to a balloon unnecessary. For the purposes of completeness, Applicant will also address the cited secondary references.

Becker et al. illustrates placement of markers 50, 52, 54 on a tubular member that extends inside of a balloon element 56. Again, the markers 50, 52, 54 are not placed on the expandable member. Rowland et al. illustrate the placement of markers in specific patterns. However, again, the markers are not illustrated as being placed on an expandable member. Therefore, neither of the secondary references provides any motivation to modify Ishida et al. to meet the claim language.

In light of the above, claim 6 is believed to be patentable over the cited combination. More particularly, none of the cited references provides actual disclosure of the placement of a radiopaque marker on an expandable member. Given that the combination lacks one element of independent claim 6, claim 6 along with dependent claims 7-9 and 13-17 are each believed to be in condition for allowance.

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Claim 18, as previously presented, recites:

18 A balloon catheter comprising:  
an elongate shaft having a lumen therein;  
a balloon attached to a distal end of the shaft and in fluid communication  
with the balloon; and  
a means for measuring positioned on the balloon.

Applicant notes that the Examiner has failed to properly consider claim 18 on its own. More particularly, there is no reference in the final action to the language "means for measuring positioned on the balloon," which is an element recited in claim 18 that is distinct from that recited in claim 6. Applicant notes that the Examiner bears the burden of establishing a *prima facie* case for unpatentability. The Examiner has failed to make note of any means for measuring positioned on the balloon in any of the cited references. The only element the Examiner has shown disposed on balloon material in the cited references appears to be the belt-type marker 24d shown in Figure 11 by Ishida et al. As discussed above, the belt-type marker 24d is not disposed on an expandable member, instead being placed on a solid chunk of balloon material disposed distal of the expandable portion of the balloon. However, it is not disclosed by Ishida et al. how one would use a single marker to perform the function of measuring.

Because the Examiner has failed to address claim 18 in the Final Office Action, and further has failed to direct Applicant to that which is believed to illustrate the claimed "means for measuring positioned on the balloon", the Examiner has failed to establish a *prima facie* case for unpatentability. In light thereof, the pending rejections should be withdrawn and claims 18-21 and 24-26 given due consideration and examination.

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In light of the above, it is believed that the Examiner has failed to state a prima facie case of unpatentability of any of pending claims 6-9, 13-21 and 24-26. Reconsideration, reexamination, and allowance of each of pending claims 6-9, 13-21 and 24-26 are respectfully requested. If a telephone interview would be of assistance, please contact the undersigned attorney at 612-677-9050.

Respectfully submitted,

Stewart M. Kume

By his Attorney,



David M. Crompton, Reg. No. 36,772  
CROMPTON, SEAGER & TUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, MN 55403-2420  
Telephone: (612) 677-9050  
Facsimile: (612) 359-9349

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